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| 10/623,908 | 07/21/2003 | Paul John Kawula | 050623.00245 | 5357 |
| 45159 | 7590 | 07/07/2009 | | |
| SQUIRE, SANDERS & DEMPSEY LLP | | | | EXAMINER |
| 1 MARITIME PLAZA | | | | PELLEGRINO, BRIAN E |
| SUITE 300 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--|--|
| Office Action Summary | Application No. 10/623,908 | Applicant(s) KAWULA, PAUL JOHN |
| | Examiner Brian E. Pellegrino | Art Unit 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on **24 April 2009**.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) **6-20,22-27,29 and 47-52** is/are pending in the application.
 4a) Of the above claim(s) **9-20 and 24-26** is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) **6-8,22,23,27,29 and 47-52** is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/09 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-8,22 are rejected under 35 U.S.C. 102(e) as being anticipated by Santini et al. (6656162). Figs. 9A-9C show the medical device is a stent. Fig. 2A illustrates a substrate 210 made of metal (col. 4, lines 4,8) that has within its surface a cavity and attachment region 220. Figs. 6A,6B illustrate that within the surface is a ceramic component, col. 12, line 14. It can also be seen there is a second ceramic component (col. 8, lines 49,50,53,55) in the form of a cap to be on the opposite side of the first ceramic component and the attachment region on the opposing

side of the first ceramic component. It can be interpreted that the second ceramic component or cap is more porous than the first ceramic component (piezoelectric element) since it is thinner, col. 8, lines 56-58). Ceramics are known to be porous. It can also be seen (Figs. 6A,6B) the ceramic *regions* contain a drug, col. 9, lines 58-67.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al. '162 in view of Alt (6099561). Santini fails to disclose the specific metal material being steel or nitinol. Alt teaches the surface of the stent is metal, col. 6, lines 50-55 and the stent metal can be steel or nitinol, col. 7, lines 44-49. It would have been obvious to one of ordinary skill in the art to use a known metal as steel or nitinol as taught by Alt with the stent of Santini et al. such that it provides the necessary properties desired.

Claims 27,29,47-50,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al. '162 in view of Brandau et al. (6709379). Santini et al. is explained *supra*. It is noted that Santini discloses layered ceramics can be used, col. 4, lines 7,8. However, Santini does not explicitly disclose the ceramics including an oxide layer between the ceramic component and the substrate. Brandau et al. teach that an oxide layer is formed for depositing layers on a substrate, col. 8, lines 2,3,15-20. It would have been obvious to one of ordinary skill in the art to utilize an oxide layer as taught by Brandau et al. with the stent of Santini et al. such that it secures the ceramic component to the substrate. Please note claim 49 includes product by

process limitations and are not governed by the process how it is achieved. Thus, the indentations of the attachment region in the substrate are fully capable of being machined or have material removed. Regarding claim 50, Santini fails to disclose the ceramic materials. Brandau et al. teach a ceramic cover layer being a ceramic oxide, col. 8, lines 21-24. It would have been obvious to one of ordinary skill in the art to select a known oxide as taught by Brandau et al. to use as the ceramic region on the Santini et al. stent since such a modification only involves routine skill in the art. With respect to claim 52, the incorporation of an oxide layer would result in a layer with the same thermal characteristics as the ceramic component by forming the oxide from the same material.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al. '162 in view of Pope et al. (6290726). Santini fails to disclose the specific ceramic material being quartz. Pope et al. teach a quartz ceramic can be used in the body for prostheses for low friction and long life, col. 11, lines 10-12, 35,36. It would have been obvious to one of ordinary skill in the art to select a known material, such as quartz as taught by Pope et al. to use as the ceramic region on the Santini et al. stent since such a modification only involves routine skill in the art. Such a modification provides a smooth surface for blood flow and is corrosion resistant.

Response to Arguments

Applicant's arguments with respect to claims 6,27 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738